



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM**

DATE: 03-DEC-2019

SUBJECT: **TCVP:** Data Evaluation Record for the Study "Determination of TCVP and DCA Residues Released from Hartz Flea and Tick Collars by Torsion Stressing"

PC Code: 083701, 083702  
Decision No.: 555265  
Petition No.: NA  
Risk Assessment Type: NA  
TXR No.: NA  
MRID No.: 50931601

DP Barcode: D454190  
Registration No.: NA  
Regulatory Action: Registration Review  
Case No.: 321  
CAS No.: 961-11-5, 22248-79-9  
40 CFR: NA

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The purpose of this memorandum is as a data evaluation record for the study, "Determination of TCVP and DCA Residues Released from Hartz Flea and Tick Collars by Torsion Stressing," MRID 50931601. Based on review of the study, there is no barrier from use of the data quantitatively for risk assessment.

**STUDY TYPE:** Determination of TCVP and DCA Residues Released from Hartz Flea and Tick Collars by Torsion Stressing

**TEST MATERIAL:** The test material was an impregnated flea and tick collar, referred to as Hartz Ultraguard (EPA Registration Number 2596-84). The collar contained 14.33% (wt/wt) tetrachlorvinphos (TCVP).

**CITATION :**

Study Author:	Joe Conti, Ken Prezpadlo, Mike Tyler, Stavros Hatzikyarakou, Jeffrey Driver, John Ross, Nicholas Driver
Title:	Determination of TCVP and DCA Residues Released from Hartz Flea and Tick Collars by Torsion Stressing
Report Date:	August 14, 2019
Performing Laboratory:	The Hartz Mountain Corporation, R&D Analytical, 640 Gotham Pkwy, Carlstadt, NJ 07072
Identifying Codes:	MRID 50931601

**SPONSORS:** The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094

### **EXECUTIVE SUMMARY:**

This report reviews the study “Determination of TCVP and DCA Residues Released from Hartz Flea and Tick Collars by Torsion Stressing” submitted by Hartz Mountain Corporation. The purpose of the study was to measure the amount of solids (dust/powder) released from a flea and tick collar and the active ingredient content of the released solids when the collar is exposed to mechanical torsion and stress. The test product was Hartz Ultraguard Collar, a flea and tick collar containing 14.33% (w/w) TCVP and 27.95% DCA.

Five collars were evaluated for this study. A section of collar was cut for use in the testing. Each collar piece was initially weighed and wiped without torsion. Then, each collar piece was subjected to mechanical torsion and stress by twisting and pulling the collar three times. The collar pieces were wiped before and after each torsion test.

The wipes were analyzed for TCVP and DCA using gas chromatography. According to the Study Report, for the wipe samples, the limit of quantitation (LOQ) was calculated to be approximately 5 µg/mL for TCVP and DCA. Fortified wipe samples were prepared at the LOQ and at a high level (approximately 300 ug/mL according to the study report; Attachment B). The fortified samples were analyzed concurrently with the study wipe papers, at both the beginning and end of the samples. The recoveries ranged from 94.1% to 107.5% for TCVP and from 105.5% to 107.3% for DCA.

The amount of dust/powder removed from the collar pieces, based on the weight difference of the collar pieces before and after the torsion tests, ranged from 5.9 mg to 11.1 mg (overall average of 7.5 mg). TCVP residues ranged from 5.3 mg to 10.6 mg in the analyzed wipes, with an average of 7.3 mg. This represents 97.2% TCVP in the mass lost from the collar piece from torsion (7.3 mg/7.5 mg \*100). DCA residues ranged from 0.07 mg to 0.09 mg in the analyzed wipes, with an average of 0.08 mg. This represents 1.1% DCA in the mass (i.e., dust) lost from the collar piece from torsion (0.08 mg/7.5 mg \*100).

The test collar piece weight was reported as 2.8 g, however, the study report notes that only 70% of the collar piece was assumed to be twisted during torsion, therefore, a weight of 2 g was assumed. Since a large collar is reported to weigh 35.6 g, the results need to be scaled by a factor of 17.8 (i.e., 35.6 g / 2 g). If the mass lost from the test collar piece was 7.5 mg due to torsion, the mass lost from a large collar would be expected to be 133.9 (i.e., 7.5 mg \* 17.8). This results in the determination that 0.38% mass (assumed to be dust) is lost from the collar due to torsional stress (i.e., 133.9 mg / 35600 mg \* 100).

**COMPLIANCE:** Signed and dated GLP and Data Confidentiality statements were provided. A Quality Assurance statement was not provided. The study sponsor waived claims of confidentiality within the scope of FIFRA Section 10(d) (1) (A), (B), or (C). The study sponsor and director stated that the study was not conducted in compliance with EPA Good Laboratory Practice Standards (40 CFR part 160), but was developed in the spirit of Good Laboratory Practice.

**CONCURRENT EXPOSURE STUDY:** No

**WAS AIR SAMPLING CONDUCTED IN CONJUNCTION WITH SURFACE SAMPLING?** No

**GUIDELINE OR PROTOCOL FOLLOWED:** The study was reviewed using applicable parts of the OPPTS Test Guidelines Series 875, Occupational and Residential Exposure Test Guidelines, Group B: 875.2100 (dislodgeable foliar residue), 875.2300 (indoor surface residue) and 875.2400 (dermal exposure).

## **I. MATERIALS AND METHODS**

### **A. MATERIALS**

#### **1. Test Material:**

Active ingredients: Tetrachlorvinphos (TCVP) and Dicapryl Adipate (DCA)  
Formulation: Hartz Ultraguard, a flea and tick collar containing 14.33% (w/w) TCVP and 27.95% DCA.  
Purity formulation: The certificate of analysis states that the test product contained 14.33% TCVP and 27.95% DCA.  
Lot # formulation: TS#14167, PP26881  
CAS #(s): TCVP: 22248-79-9  
Other Relevant Information: EPA Registration No. 2596-84 (dog collar)

#### **2. Relevance of Test Material to Proposed Formulation(s):**

The test material is one of the currently registered tetrachlorvinphos dog collars.

### **B. STUDY DESIGN**

The study protocol, signed by the Study Director and Study Sponsor on August 8, 2019, was provided with the study report. No deviations or amendments were noted in the study report.

**1. Test location:** The study was conducted at Hartz Mountain Corporation in New Jersey.

**2. Test System:** Five Hartz Ultraguard collars were used in the study. A section of collar was cut for use in the testing. Each collar piece was subjected to mechanical torsion and

stress by twisting and pulling the collar piece three times.

**1. Physical State of Formulation as Applied:**

The test substance was an impregnated tick and flea collar.

**4. Torsion Test and Sampling Procedures:**

Method and Equipment: Five pieces, each 58 mm, of collar were used for the study. According to the study protocol, each piece was initially stretched by holding the collar piece by the ends with gloved fingers and firmly pulling. This action is consistent with label language which directs the user to, “unroll and stretch to activate insecticidal generator.” The collars were then weighed and wiped without torsion. The wipes were 3” squares of Kimberly-Clark Wypall L20 paper wiper (according to the provided study protocol). Three torsion tests were performed on each collar piece and the weight after each torsion and wiping was recorded.

Sampling Procedure(s): According to the study protocol, after the collar piece was initially stretched, the initial weight was recorded. Prior to the first torsion cycle, the collar pieces were wiped and the wipe placed in a 2 oz glass bottle. The collar piece weight was then recorded. The torsion tests were performed by gripping each collar piece at each end with fingers and twisting 10 times for 180 degrees. After each torsion cycle, the collar pieces were wiped and the weight recorded.

Surface area sampled: The study noted that the surface area of the collar pieces was 1752 mm<sup>2</sup>.

Sampling Time: Not reported.

Replicates Five collar pieces were sampled in this study.

Times of sampling: Not applicable.

**5. Sample Handling:**

After wiping, the wipes were placed in a 2 oz glass bottle.

**6. Analytical Methodology:**

The study report states that the wipes were analyzed for TCVP and DCA according to the Test Method TM #537-0 (Attachment B of the study report).

Extraction method(s):

Wipes: According to the study report (p.7), each collar wipe was diluted with 15 mL of acetone, placed on a vortex for one minute, and shaken in a mechanical shaker for 30 minutes. However, according to TM #537-0 (provided as an attachment to the study report), the wipes are placed in 2 oz bottles and 25.0 mL of acetone is added. The bottles are placed on an automatic shaker for at least 30 minutes and then 3.0 mL is transferred to a 25 mL volumetric flask and diluted to volume with acetone. The study report does not address this inconsistency in extraction method description.

Detection method(s): Analysis was performed using gas chromatography.

Method validation: Method validation results were not presented in the study report.

According to the Study Report, for the wipe samples, the limit of quantitation (LOQ) was calculated to be approximately 5 µg/mL for TCVP and DCA.

Instrument performance and calibration: For TM #537-0, the study report attachment notes that the standard calibration should involve four injections (one of each level, lowest to highest). It also notes that the calibration correlation coefficient should be 0.99 or higher and the percent recovery for each of the fortified samples should be between 70 and 130%.

Quantification: Quantitation was achieved using peak area ratios from internal and external calibration standards.

## **8. Quality Control:**

Lab Recovery/Field Blanks/Field Recovery: Field blanks and field recoveries are not applicable. Laboratory fortified wipe paper samples were prepared at the LOQ and at a high level (approximately 300 ug/mL according to the study report; Attachment B). The recoveries were all within acceptable limits and ranged from 94.1% to 107.5% for TCVP and from 105.5% to 107.3% for DCA.

Formulation: The test product is an impregnated collar containing 14.33% (w/w) TCVP and 27.95% DCA.

Tank mix: Not applicable.

Travel Recovery: Not applicable

Storage Stability: Not applicable.

## **II. RESULTS AND CALCULATIONS**

The study report presented the change in mass of the collar (pre-torsion and after each of the three torsion tests), and the amounts of TCVP and DCA found in the wipe samples taken after each torsion test. These results are presented in Table 1 and have been verified by HED.

As shown in Table 1, the amount of dust/powder removed from the collars, based on the weight difference of the collars before and after the torsion tests, ranged from 5.9 mg to 11.1 mg (overall average of 7.5 mg). TCVP residues ranged from 5.3 mg to 10.6 mg in the analyzed wipes, with an average of 7.3 mg. This represents 97.3% TCVP in the mass (i.e., dust) lost from the collar from torsion ( $7.3 \text{ mg} / 7.5 \text{ mg} * 100$ ). DCA residues ranged from 0.07 mg to 0.09 mg in the analyzed wipes, with an average of 0.08 mg. This represents 1.1% DCA in the mass (i.e., dust) lost from the collar from torsion ( $0.08 \text{ mg} / 7.5 \text{ mg} * 100$ ).

The test collar piece weight was reported as 2.8 g, however, the study report notes that only 70% of the collar was assumed to be twisted during torsion, therefore, a weight of 2 g was assumed. Since a large collar is reported to weigh 35.6 g, the results need to be scaled by a factor of 17.8 (i.e.,  $35.6 \text{ g} / 2 \text{ g}$ ). If the mass lost from the test collar piece was 7.5 mg due to torsion, the mass lost from a large collar would be expected to be 133.9 mg (i.e.,  $7.5 \text{ mg} * 17.8$ ). This results in the determination that 0.38% mass (assumed to be dust) is lost from the collar due to torsional stress (i.e.,  $133.9 \text{ mg} / 35600 \text{ mg} * 100$ ).

COLLAR SAMPLE		Collar Weight		Mass Loss (mg)	% Mass Loss <sup>2</sup>	TCVP residues in wipe samples		DCA residues in wipe samples		TCVP/DCA Ratio
		(grams)	(mg)			(ug)	(mg)	(ug)	(mg)	
Collar #1 (58mm)	Before Wipe	2.8547	2854.7	---		---	---	---	---	---
	WIPE 1 (no torsion)	2.8491	2849.1	5.6		6563.3	6.5633	16.6	0.0166	395.4
	TORSION 1 WIPE 2	2.8435	2843.5	5.6	0.28%	5280.8	5.2808	35.3	0.0353	149.6
	TORSION 2 WIPE 3	2.8396	2839.6	3.9	0.20%	3962.9	3.9629	35.8	0.0358	110.7
	TORSION 3 WIPE 4	2.838	2838	1.6	0.08%	1312.4	1.3124	18.8	0.0188	69.8
	Total Mass Loss <sup>1</sup>			11.1	0.56%		10.6		0.09	
Collar #2 (58mm)	Before Wipe	2.7461	2746.1	---		---	---	---	---	---
	WIPE 1 (no torsion)	2.7418	2741.8	4.3		4876.3	4.8763	15.2	0.0152	320.8
	TORSION 1 WIPE 2	2.7389	2738.9	2.9	0.15%	3302.7	3.3027	29.5	0.0295	112.0
	TORSION 2 WIPE 3	2.7363	2736.3	2.6	0.14%	2645.4	2.6454	28.3	0.0283	93.5
	TORSION 3 WIPE 4	2.735	2735	1.3	0.07%	1311.5	1.3115	24.3	0.0243	54.0
	Total Mass Loss			6.8	0.35%		7.3		0.08	
Collar #3 (58 mm)	Before Wipe	2.769	2769	---		---	---	---	---	---
	WIPE 1 (no torsion)	2.7668	2766.8	2.2		2294.6	2.2946	12.8	0.0128	179.3
	TORSION 1 WIPE 2	2.7648	2764.8	2	0.10%	1894.6	1.8946	21.8	0.0218	86.9
	TORSION 2 WIPE 3	2.7623	2762.3	2.5	0.13%	2278.4	2.2784	29.4	0.0294	77.5
	TORSION 3 WIPE 4	2.7609	2760.9	1.4	0.07%	1138.7	1.1387	22.1	0.0221	51.5
	Total Mass Loss			5.9	0.31%		5.3		0.07	
Collar #4 (58 mm)	Before Wipe	2.818	2818	---		---	---	---	---	---
	WIPE 1 (no torsion)	2.8129	2812.9	5.1		5941.1	5.9411	17.7	0.0177	335.7
	TORSION 1 WIPE 2	2.8097	2809.7	3.2	0.16%	3258.7	3.2587	28.4	0.0284	114.7
	TORSION 2 WIPE 3	2.8064	2806.4	3.3	0.17%	3192.5	3.1925	31.5	0.0315	101.3
	TORSION 3 WIPE 4	2.8053	2805.3	1.1	0.06%	1356.1	1.3561	25.1	0.0251	54.0
	Total Mass Loss			7.6	0.39%		7.8		0.09	
Collar #5 (58 mm)	Before Wipe	2.8822	2882.2	---		---	---	---	---	---
	WIPE 1 (no torsion)	2.8798	2879.8	2.4		3167.6	3.1676	17.7	0.0177	179.0
	TORSION 1 WIPE 2	2.8775	2877.5	2.3	0.11%	2162	2.162	26.7	0.0267	81.0
	TORSION 2 WIPE 3	2.8749	2874.9	2.6	0.13%	2217.9	2.2179	27.1	0.0271	81.8
	TORSION 3 WIPE 4	2.8736	2873.6	1.3	0.06%	1232.9	1.2329	23.3	0.0233	52.9
	Total Mass Loss			6.2	0.31%		5.6		0.08	
<b>Average</b>		<b>2.8</b>		<b>7.5</b>	<b>0.38%</b>		<b>7.3</b>		<b>0.08</b>	

1. Total mass lost does not include the mass lost from the first wipe before the torsion testing.

2. Percent mass loss = (mass loss after torsion wipe, mg) / (collar weight, mg, \* 0.7). The collar weight is multiplied by 0.7 to account for the fact that only 70% of the collar piece was assumed to be twisted during torsion.